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. 10/626,069	07/24/2003	Garret D. Cawthon	37013-6	9758
52450 7590 04/18/2007 KRIEG DEVAULT LLP ONE INDIANA SQUARE			EXAMINER	
			CARTER, KENDRA D	
SUITE 2800 INDIANAPOLIS, IN 46204-2079			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

		Application No.	Applicant(s)				
Office Action Summary		10/626,069	CAWTHON, GAF	CAWTHON, GARRET D.			
		Examiner	Art Unit				
		Kendra D. Carter	1617				
Period fo	The MAILING DATE of this communicat or Reply	ion appears on the cover sheet v	with the correspondence a	ddress			
WHIC - External after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR CHEVER IS LONGER, FROM THE MAIL asions of time may be available under the provisions of 37 SIX (6) MONTHS from the mailing date of this communic period for reply is specified above, the maximum statutor to reply within the set or extended period for reply will, reply received by the Office later than three months after the patent term adjustment. See 37 CFR 1.704(b).	ING DATE OF THIS COMMUN CFR 1.136(a). In no event, however, may a ation. Ty period will apply and will expire SIX (6) MO by statute, cause the application to become a	IICATION. a reply be timely filed DNTHS from the mailing date of this of ABANDONED (35 U.S.C. § 133).				
Status							
1)⊠	Responsive to communication(s) filed o	n 15 November 2006					
2a)□	· · · · · · · · · · · · · · · · · · ·	☐ This action is non-final.					
3)	· _						
,—	closed in accordance with the practice u	•	•				
Dispositi	on of Claims						
4)⊠	Claim(s) <u>39-53,57,60,74-76 and 87-94</u> i	s/are pending in the application					
-	4a) Of the above claim(s) is/are withdrawn from consideration.						
	Claim(s) is/are allowed.						
6)⊠	6)⊠ Claim(s) <u>39-53,57,60,74-76 and 87-94</u> is/are rejected.						
7)	<u> </u>						
8)□	Claim(s) are subject to restriction	and/or election requirement.					
Applicati	on Papers						
9)[]	The specification is objected to by the Ex	xaminer					
· —	•		by the Examiner				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
	Replacement drawing sheet(s) including the	- · · · · · · · · · · · · · · · · · · ·	• •	FR 1.121(d).			
11)	The oath or declaration is objected to by						
Priority ι	ınder 35 U.S.C. § 119						
	Acknowledgment is made of a claim for a laim for a lai	foreign priority under 35 U.S.C.	§ 119(a)-(d) or (f).				
u),	1. Certified copies of the priority doc	uments have been received					
	2. Certified copies of the priority doc		Application No				
	3. Copies of the certified copies of the		· · · · · · · · · · · · · · · · · · ·	l Stage			
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* 5	See the attached detailed Office action fo		ot received.				
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Attachmen	t(s)		į.				
	e of References Cited (PTO-892)	4) Interview	Summary (PTO-413)				
	e of Draftsperson's Patent Drawing Review (PTO- nation Disclosure Statement(s) (PTO/SB/08)		o(s)/Mail Date f Informal Patent Application				
	r No(s)/Mail Date	6) Other: _					

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 15, 2006 has been entered.

Claims 39-53, 57, 60, 74-76, and 87-94 are pending. Claims 1-38, 54-56, 58-59, 61-73, and 77-86 are cancelled. Claims 39, 60, and 76 are amended and claims 87-94 are new.

In light of the amendment to the claims, the 35 USC 112, first paragraph rejection of claims 39-53, 57-60 and 74-82 is withdrawn.

In light of the amendment to the claims, the 35 USC 112, second paragraph rejection of claims 39-53, 57, 59, 60 and 74-82 is withdrawn.

In light of the amendment to the claims, the 35 USC 103 rejection of claims 39-50 and 57-60 as being unpatentable over Adams et al. in view of Moss and Mulder is withdrawn.

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In light of the amendment to the claims, the 35 USC 103 rejection of claims 41-43 and 60 as being unpatentable over Adams et al. in view of Moss and Mulder, and further in view of Boussouira et al. is withdrawn.

In light of the amendment to the claims, the 35 USC 103 rejection of claims 39, 51 and 52 as being unpatentable over Adams et al. in view of Neubourg is withdrawn.

Applicant's arguments with respect to claims 39-53 and 57-86 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-53, 57, 60, 74-76, and 87-94 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The negative proviso "wherein the dispenser is not an aerosol device" is not supported by the specification. Moreover, the Applicant defines the aerosol device as "another atomizing spray dispenser that may be used in accordance with the invention" (see page 25, paragraph 3, lines 1-3).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39, 49, 57, 74, 76, and 88 are rejected under 35 U.S.C. 102(b) as being anticipated by Heilig (US 3,079,299).

Heilig teaches a self-propelling medicinal ointment composition and method of application comprising mineral oil, a polyethylene resin (i.e. solid particulate material) and a volatile propellant for dispensing and applying to the part of the body to be treated (see title and column 1, lines 11-16; addresses claim 39). The preferred mineral oil is petrolatum (see column 8, lines 43 and 44; addresses claim 49). The composition is adapted to be atomized from a fluid-tight container (see column 1, lines 30-34), in which

the volatile propellant is a liquefied compressed gas provided in sufficient proportion in the ointment composition to atomize it through the valve of the container in which it is stored under pressure to produce a uniform porous coating of the polyethylene ointment base with medicament dispersed therein (see column 2, lines 41-47; addresses claims 39, 74 and 88). The primary medicament includes an antiseptic, bactericidal, or antibiotic (see column 2, lines 56-58; addresses claim 57) in an aqueous or alcoholic solution with an emulsifying agent (see column 8, lines 5-9; addresses claims 39 and 57). In 20 cases of dermatitis, including diaper rash, the spray provided rapid relief (see column 5, lines 42-45; addresses claim 39). In regards to claim 76, the volatile compound evaporating after passage through the atomizing spray dispenser an inherent property of a "volatile" compound released under pressure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(1) Claims 40-50, 52, 53, and 60 rejected under 35 U.S.C. 103(a) as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Paul et al. (US 6,217,890 B1), and in further view of Clark et al. (US 6,103,245).

Heilig teachings are as applied to claims 39, 49, 57, 74, 76, and 88 above.

Heilig does not teach zinc oxide as the particulate or its average particle size (claims 40-43 and 60). Silicone oil, particularly cyclomethicone or dimethicone and derivatives thereof is not taught (claim 45). Talc, paraffin wax, microcrystalline wax, calamine, kaolin, cod liver oil, plant based oil, or bees wax is also not taught (claims 46-48 and 50-53).

Paul et al. teaches an absorbent article for absorbing body fluids and exudates, such as disposable diapers and adult incontinence garments (see column 1, lines 19-23), which includes a lotion formulation or treatment composition which provides a skin health benefit, and/or have a reduced viability of microorganisms (see column 2, lines 56-58). The lotion formulation includes an emollient, a wax, optionally a viscosity enhancer, and other ingredients (see column 13, lines 57-59 and 64). The emollients

act as lubricants to reduce the abrasiveness of the topsheet to the skin and, upon transfer to the skin, help to maintain the soft, smooth and pliable appearance of the skin (see column 13, lines 66, 67 to column 14, lines 1 and 2). Suitable emollients include vegetable based oils, mineral oils, natural or synthetic oils, silicone oils, lanolin and lanolin derivatives, kaolin and kaolin derivatives and the like and mixture thereof (se column 14, lines 3-5; address claims 39, 44, 48, 49, 57). The wax in the lotion formulations primarily functions as an immobilizing agent for the emollient and any active ingredient. In addition to immobilizing the emollient and reducing it's tendency to migrate, the wax in the lotion formulation provides a tackiness, which improves the transfer to the skin of the wearer. The presence of the wax also modifies the mode of transfer in that the lotion tends to fracture or flake off instead of actually rubbing off onto the skin of the wearer which can lead to improved transfer to the skin. The wax may further function as an emollient, occlusive agent, moisturizer, barrier enhancer and combinations thereof (see column 14, lines 31-43). Suitable waxes include beeswax. C30 alkyl dimethicone, jojoba oil, microcrystalline wax, paraffin and mixtures thereof (see column 14, lines 44, 47, 49, 52-54, and 59; addresses claims 45, 46, 52, 53 and 57). A viscosity enhancer increases the viscosity to help stabilize the formulation on the bodyfacing surface on the topsheet and reduce migration and improve transfer to the skin (see column 15, lines 6-9). A suitable viscosity enhancer is polyethylene, talc or mixtures thereof (see column 15, lines 18 and 20; addresses claim 48). ingredients such as diaper rash skin protectants, which protect the injured or exposed skin or mucous membrane surface from harmful or annoying stimuli are included (see

column 15, lines 31-36). Suitable active ingredients include calamine, dimethicone, cod liver oil, kaolin and its derivatives, lanolin and its derivatives, mineral oil, talc, zinc oxide and mixture thereof from about 0.10 to about 95 weight percent (see column 15, lines 40-44; addresses claims 39, 40, 47-50, 53 and 57). To further enhance the benefit to the wearer, antimicrobial, antifungal, antiseptic, colarants, and fragrances can be added (see column 15, lines 54, 55, 61, 62, and column 16 lines 6 and 7; addresses claim 57). The treatment composition is added to the topsheet by spraying (see column 23, lines 59 and 60).

Clark et al. teaches a composition for superior, longer-lasting barrier formulation as a protective barrier for incontinent patients along with managing diaper rash in humans (see column 4, lines 55-59). The inorganic barrier component zinc oxide is used and should be micronized to a particle size such that the barrier composition itself, after the addition of the inorganic component, is a smooth homogeneous composition that is essentially grit free (see column 7, lines 5-9 and claim 20). Zinc oxide has a mild astringent, protective and antiseptic action. Thus it is often used in the treatment of skin disorders and a number of epidermal infections (see column 7, lines 11-14).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and calamine, dimethicone, cod liver oil, kaolin and its derivatives, lanolin and its derivatives, mineral oil, talc, zinc oxide and mixture thereof because Paul et al. teaches the following: (1) the above ingredients

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are diaper rash skin protectants, which protect the injured or exposed skin or mucous membrane surface from harmful or annoying stimuli (see column 15, lines 31-36); (2) the composition may be sprayed (see column 23, lines 59 and 60). Therefore, using a known diaper rash skin protectant would be benefical in a method to treat diaper rash. Additionally, since the composition can be formulated into a spray, the above ingredients can be used in the method of Heilig.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and the average particle size of zinc oxide as disclosed in claims 40-43 and 60 because Clark et al. teaches that zinc oxide should be micronized to a particle size such that the barrier composition itself, after the addition of the inorganic component, is a smooth homogeneous composition that is essentially grit free (see column 7, lines 5-9 and claim 20). One skilled in the art would be able to determine the optimal particle size of zinc oxide by routine experimentation.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and beeswax, C30 alkyl dimethicone, jojoba oil, microcrystalline wax, paraffin and mixtures thereof (see column 14, lines 44, 47, 49, 53-54, and 59) is because Paul et al. teaches the following: (1) the above ingredients modify the mode of transfer in that the lotion tends to fracture or flake off instead of actually rubbing off onto the skin of the wearer which can lead to improved

transfer to the skin. Additionally, the ingredients further function as an emollient, occlusive agent, moisturizer, barrier enhancer and combinations thereof (see column 14, lines 31-43); (2) the composition may be sprayed (see column 23, lines 59 and 60). Therefore, using ingredients that benefit the wearer of a diaper with the above properties would be beneficial in a method to treat diaper rash. Additionally, since the composition can be formulated into a spray, the above ingredients can be used in the method of Heilig.

(2) Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Steuart et al. (US 5,330,756).

Heilig teachings are as applied to claims 39, 49, 57, 74, 76, and 88 above.

Heilig does not teach calendula extract, chamomile extract, comfrey extract, or a plant based oil.

Steuart et al. teaches a method of treating a variety of skin conditions, such as diaper rash (see column 6, lines 19 and 20) with a therapeutic formulation comprising concentrated fluid plant extracts such as *S. officinale* (see abstract, lines 4, 5, and 11-14; column 4, line 45; and column 5, lines 29-32) and olive oil, castor oil, and jojoba oil

(i.e. plant based oils; see column 10, example B2 and B3). Alcohol or glycol extract solutions of *S. officinale*, which is called "comfrey" has been recognized for decades for its healing properties, particularly for its ability to stimulate epithelial development externally in the case of skin damage (see column 1, lines 21, 21, and 61-64). The formulations are formulated into a spray (see column 5, lines 50-53). In oil and water emulsion formulations, the oil is the dispersed phase for the purpose of protecting, moisturizing, and stimulating the healing processes of skin or mucous membrane (see column 5, lines 40-44).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and comfrey extract and a plant based oil because Steuart et al. teaches a method of treating diaper rash with and comfrey extract in a variety of plant based oils. The benefit of using comfrey extra in an oil is because of the following teachings by Steuart et al.: (1) comfrey extracts have been recognized for decades for its healing properties, particularly for its ability to stimulate epithelial development externally in the case of skin damage (see column 1, lines 21, 21, and 61-64); and (2) the oil is the dispersed phase for the purpose of protecting, moisturizing, and stimulating the healing processes of skin or mucous membrane (see column 5, lines 40-44). Additionally, since the composition can be formulated into a spray, the above ingredients can be used in the method of Heilig.

(3) Claims 74, 75, 87, 89, 93 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Ando (US 5,881,925).

Heilig teachings are as applied to claims 39, 49, 57, 74, 76, and 88 above.

Heilig does not teach a pump spray dispenser and a pressure release device (claims 74, 75 and 87). A piston-style dispenser, wherein pressure is maintained on the composition by pressure of the piston is also not taught (claim 89). Lastly, a manually actuated or reciprocating actuator spray delivery mechanism is not taught (claims 93 and 94).

Ando teaches a atomizer of the reciprocating pump type with a push button that is capable of being pressed with a finger, a piston which is pushed down by pressing the push button, a pressure chamber formed with the cylinder and the piston that has an inlet leading to the inside of the container and an outlet leading to the internal passage in the push button, the outlet of the pressure chamber moves against the force increased when the piston is pressed by the push button to open the above outlet (see column 1, lines 46 and 52-64; addresses claims 74, 75, 87, 89 and 94). Conventionally, atomizers that spray a mixture of liquid and powder are available such that the user shakes the mixture well in the container and then the push button is pressed. The atomizing tube is pushed in and opens the valve and the mixture is atomized through

the nozzle (see column 1, lines 13, 14, and 18-23; addresses claim 93). The reciprocating pump type device provides an atomizer that is capable of stirring a mixture sufficiently and atomizing both powder and a liquid when used (see column 1, lines 24-32).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and a reciprocating pump type device with a piston-style dispenser, wherein pressure is maintained on the composition by pressure of the piston because Ando teaches the following: (1) reciprocating pump type with a push button that is capable of being pressed with a finger, a piston which is pushed down by pressing the push button, a pressure chamber formed with the cylinder and the piston that has an inlet leading to the inside of the container and an outlet leading to the internal passage in the push button, the outlet of the pressure chamber moves against the force increased when the piston is pressed by the push button to open the above outlet (see column 1, lines 46 and 52-64); and (2) The reciprocating pump type device provides an atomizer that is capable of stirring a mixture sufficiently and atomizing both powder and a liquid when used (see column 1, lines 24-32). Being that the applicant's method comprises a liquid and solid, this device would be suitable to deliver the diaper rash composition.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and a spray delivery comprising a manually actuated spray delivery mechanism is because as taught by Ando, it is the conventional way to atomize liquid and solid compositions (see column 1, lines 13, 14, and 18-23). Being that the applicant's method comprises a liquid and solid, this device would be suitable to deliver the diaper rash composition.

(4) Claims 90 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Davies et al. (US 5,169,037).

Heilig teachings are as applied to claims 39, 49, 57, 74, 76, and 88 above.

Heilig does not teach a bag-in-can-style dispenser, wherein the pressurized compartment is a polymeric bag received inside a rigid can or wherein the pressure is maintained upon the composition by a pressurizing gas received in the can and externally to the bag (claims 90 and 91).

Davies et al. teaches a product dispenser with a product bag. Pressure in the container surrounding the bag determines the dispensing pressure (see abstract, lines 1-4; addresses claims 90 and 91). The product bag is constructed of a suitable barrier material, which may take the form of a gas impervious material (see column 2, lines 6-8

and 31-33) and the height should be approximately equal to the different between the in inside can height (see column 7, line 51 and 52). The pressure regulating system is configured so as to permit product dispensing with an unrestricted orientation of the product dispenser while avoiding loss in product dispensing pressure or interruption of product dispensing (see column 2, lines 59-64). Additionally, the product has the following advantages: (1) the capability of choosing a starting pressure depending upon the amount of product fill in the product bag together with a given can size and product bag size; and (2) off the shelf actuators which are cheaper and less prone to clogging than special units designed for wide range of pressure in the dispensing of the product can be used (see column 14, lines 36-45).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and a bag-in-can-style dispenser, wherein the pressurized compartment is a polymeric bag received inside a rigid can or wherein the pressure is maintained upon the composition by a pressurizing gas received in the can and externally to the bag because Davies et al. teaches the above bag-in-can style dispenser, which permits product dispensing with an unrestricted orientation of the product dispenser while avoiding loss in product dispensing pressure or interruption of product dispensing (see column 2, lines 59-64). Additionally, the product has the following advantages: (1) the capability of choosing a starting pressure depending upon the amount of product fill in the product bag together with a given can size and product bag size; and (2) off the shelf actuators which are cheaper and less

prone to clogging than special units designed for wide range of pressure in the dispensing of the product can be used (see column 14, lines 36-45).

(4) Claims 90 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Hanson et al. (US 5,249,747).

Heilig teachings are as applied to claims 39, 49, 57, 74, 76, and 88 above.

Heilig does not teach a bag-in-can-style dispenser, wherein the pressurized compartment is a polymeric bag received inside a rigid can. Also, an elastic shapememory bag wherein the pressure is maintained upon the composition by maintaining the bag in an expanded state is not taught.

Hanson et al. teaches a dispensing system for viscous fluids having a viscosity of greater than 60 cps (see column 3, lines 44-48), particularly vegetable oil containing compositions in closed pressurized containers such as bladder packs (see column 2, lines 8-13).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and the specific bag-in-can-style

dispenser, bladder pack container (Applicant refers to an elastic shape-memory bag wherein the pressure is maintained upon the composition by maintaining the bag in an expanded state as a bladder pack container on page 25, paragraph 1, lines 6-8) because Hanson et al. teaches a dispensing system for viscous vegetable oil containing compositions in closed pressurized containers such as bladder packs (see column 2, lines 8-13). Being that the applicant's method comprises a fluid base material with a viscosity from about 1 to 1000 cps (see specification page 12, paragraph 2, lines 1-4) that does not run off the skin (see claim 39) this device would be suitable to deliver the diaper rash composition.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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KDC

SREENI PATANABHAN SREENI PATANABHAN SREENISORY PATENT EXAMINER